**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
NORFOLK DIVISION**

HILL-ROM COMPANY, INC.,	)	
HILL-ROM SERVICES, INC., and	)	
HILL-ROM MANUFACTURING, INC.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Case No. 2:14-CV-187-RGD-LRL
	)	
GENERAL ELECTRIC COMPANY,	)	
	)	
Defendant.	)	
	)	

DECLARATION OF ROBERT L. WALLACE

I, Robert L. Wallace, hereby declare and state as follows:

1.   I make this declaration in connection with General Electric Company's ("GE") opposition to the motion for preliminary injunction filed by Hill-Rom Company, Inc., Hill-Rom Services, Inc., and Hill-Rom Manufacturing, Inc. (together, "Hill-Rom"). I have personal knowledge of the facts set forth herein and, if called as a witness, would competently testify to such facts.

2.   I am currently the Global Product Manager for AgileTrac at GE Healthcare. My team is responsible for product management. My team is located in Richmond, Virginia. I supervise approximately 3 employees.

3.   I understand that the accused product in this case is GE's AgileTrac™ Hand Hygiene system ("the GE Hand Hygiene System") and its associated hardware and software. The GE Hand Hygiene System operates on a Real-Time Location System network ("RTLS") that is commonly found in hospitals. RTLS was traditionally used to track equipment but has been

expanded to accommodate hand-hygiene products. I have personal knowledge of all aspects of

the GE Hand Hygiene System, am knowledgeable about how it functions.

4.   The GE Hand Hygiene System consists of three, independent and functionally

distinct operations. The first operation is the Location Operation, which records the location of

personnel. The second operation is the Hand Hygiene Dispense Operation, which records usage

of hand-hygiene dispensers. These two, separate processes generate separate data streams that

are compared (but not combined) once per day by the third operation—the Compliance Engine—

to measure hand hygiene compliance. I discuss each operation below.

Location Operation

5.   The components of the Location Operation include signposts located in hospital

rooms, badges worn by hospital personnel, readers spaced sporadically throughout the hospital,

and the GE RTLS software. I discuss each of these components below.

6.   The room signposts are small devices that mounted on or near the ceiling of

hospital rooms. The signposts emit a coded infrared light approximately every two seconds,

indicating the room number associated with the signpost. The signposts are visually identical to

each other, but the light that they emit is uniquely coded to indicate the respective room number.

7.   The badges are worn by hospital personnel and are equipped with an infrared

receiver and a radio frequency transmitter. The infrared receiver detects the infrared light emitted

by the signposts, and the radio transmitter reports the badge's location to a reader in intervals of

every few seconds to about 30 seconds. When a healthcare worker enters a room, the badge will

detect the infrared light from the signpost and report the worker's location to the reader using the

radio transmitter. When the healthcare worker exits the room, this information is indicated by the

badge no longer seeing the infrared light from the signpost. I refer to the information collected

upon entry and exit of a room as the Location data or signals. A room is defined by a "light cone" created by the signpost infrared transmission. A "light cone" can also be created in a hallway, closet, large waiting area, or load docking. A typical embodiment is room walls containing the "infrared light cone" thereby creating a room.

8.   The badge beacon rate is variable from every few seconds to every 30 seconds. When a badge sees a new coded infrared light source from a signpost it will within a few seconds transmit that it sees this new coded infrared light via radio frequency. The badge then waits about 10 seconds before beaconing again, if it still sees the same coded infrared light source. At this point, the badge will beacon about every 30 seconds, if it still sees the same coded infrared light source. This is done to preserve the battery life of the badge. Fewer beacons is less power drain on the battery and thereby longer life of the badge.

9.   The readers are radio receivers that look like wireless routers and are sporadically placed around the hospital. The readers are not located in the hospital rooms but are instead located in the hallways. The readers receive radio frequency signals from the personnel badges, using similar technology as a cordless phone in one's home.

10.   Once a reader receives Location data from a badge, the reader forwards the badge's location to the GE RTLS software over the hospital's wired TCP/IP network. The GE RTLS software processes the positioning logic and determines whether the data should be ignored or forwarded to a software layer called ActiveMQ, which is an enterprise service bus.[1]

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[1] Approximately 97% of the data transmitted by the badges is ignored because the badges continue to report their location even if the person wearing the badge has not moved or moves around within the same room.

11.   A Data Bridge subscribes to ActiveMQ for the positioning messages and pushes the position message to the Hand Hygiene Manager in the Microsoft Azure Cloud. The Hand Hygiene Manager then writes the position information to a database for storage.

Hand Hygiene Dispense Operation

12.   The components of the Hand Hygiene Dispense Operation include hand sanitization dispensers, as well as the badges worn by hospital personnel, the readers spaced sporadically throughout the hospital, and the GE RTLS software.

13.   The dispensers are located in hospital rooms and are required to be used within forty-five seconds of GE's software determining that a healthcare worker entered the room, and within ninety seconds of the person exiting the room. An exemplary dispenser is the Gojo Purell dispenser. There may also be dispensers within a few meters outside of a room in the hallway, or between rooms. Thus, a healthcare worker can elect to use the dispenser in the hallway or between rooms rather than the dispenser in the room.

14.   The dispensers contain either an embedded proximity module or a sidecar, both containing a radio-frequency transmitter and a proximity sensor. The primary difference between the embedded module and the sidecar is that the transmitter and sensor are mounted on the outside of the dispenser in the sidecar version, but these components are mounted inside the dispenser in the embedded version. The sidecar employs a simple magnetic switch that can be retrofitted and attached to an existing hand-sanitization dispenser, so as to avoid the need to purchase a new dispenser with the embedded module.

15.   The embedded module/sidecar transmits a beacon to the reader approximately every six seconds; the reader forwards these messages to the GE RTLS software, which the GE RTLS software ignores. When a person actuates the dispenser to dispense the sanitization liquid,

the proximity sensor in the embedded module/sidecar emits a radio signal that searches for the nearest badge. If the nearest badge receives the signal from the dispenser, the badge beeps and sends asignal to the reader, including the badge ID and the dispenser ID, indicating that the badge was just matched with a dispenser. The sidecar/embedded module sends a separate signal to the reader via radio frequency, indicating that the dispenser was just used and that it found a badge, or didn't find a badge.[2] The radio signal sent from the dispenser sidecar/embedded module to the reader includes the dispenser's ID number and a Boolean if the dispenser saw a badge or not. The reader forwards the messages in octal format to the GE RTLS software via the hospital's TCP/IP network.

16.   The GE RTLS software then constructs two messages. The first message is a Flag Change, indicating that the badge was matched with a dispenser. The second message is an Attribute Change, indicating that the dispenser was used. The GE RTLS software pushes both messages to ActiveMQ. The Data Bridge subscribes to ActiveMQ and filters data by staff badge, as there maybe asset badges in the room on wheel chairs, infusion pumps, or patients. Upon seeing a Flag Change message associated with a staff badge, Data Bridge starts a six-second timer. If within six seconds an Attribute Change is seen with a matching dispenser ID, the Data Bridge creates a "Clinician Sanitized Message" with the ID of the dispenser that was matched to the staff member. If no Attribute Change with a matching dispenser ID is seen, the Data Bridge creates a "Clinician Sanitized Message Without Dispenser ID."

17.   Data Bridge then pushes the "Clinician Sanitized Message," created from the staff worn badge, and the dispenser actuated telemetry from the embedded/sidecar module to the

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[2] If a person actuates the dispenser but is not wearing a badge (and if there is no badge nearby), the dispenser will send a signal to the reader indicating that the dispenser was just used, but the signal will not contain information indicating that it found the nearest badge.

Hand Hygiene Manager in the Microsoft Azure Cloud, and the Hand Hygiene Manager writes

the messages to a database for storage.

Compliance Engine

18.   Although the GE RTLS software receives data from the readers throughout the

day, the compliance data is only accessed once per day by the Compliance Engine hosted in the

Microsoft Azure Cloud. This occurs at approximately 1:45 AM ET, at which time, the

Compliance Engine compares the Location data generated by the badges, and the actuated

dispenser module telemetry, and the Clinician Sanitized Messages that were created based on

usage of the dispensers in either the hospital rooms or the hallways. The data from these three

sources are correlated using the time stamps from these data flows. The Compliance Engine

reviews each instance of Location data and determines whether there is a corresponding

Clinician Sanitized Message or dispenser actuation within forty-five/ninety seconds of the time

stamp on the Location record. This process creates what we refer to as an Encounter Record. At

4:15 AM ET, a Tableau extract is created for presentation of the results of the comparison for

visualization on the dashboard. Tableau is third-party software that is a business intelligence

tool. The data presented shows the percentage of times a person washed her hands based on the

number of opportunities she had to wash her hands.

19.   Tableau shows the hospital user three dashboards. One is a high-level executive

overview, another is a unit manager view, and the third is a peer compliance view. These

dashboards show the percentage of the times that a person washed her hands based on the

number of opportunities she had to wash her hands, and generate reports showing the average

compliance percentage over a period of time. The executive overview dashboard has three

charts: (1) compliance and encounter trend, (2) role compliance and encounter duration, and (3)

staff role by location compliance. The unit manager and peer compliance views show individual names along with the total opportunities that each individual had to wash her hands over a period of time, and the percentage of those opportunities that each person actually washed her hands.

Additional Information Concerning the GE Hand Hygiene System

20.   The following paragraphs provide additional, relevant information about the GE Hand Hygiene System. For example, the GE Hand Hygiene System (i) does not track movement among zones or rooms as a variable for determining compliance; (ii) cannot determine if a person washed her hands since her most recent exposure to a zone other than her current zone; (iii) cannot determine if a healthcare worker is contaminated, has been in a contaminated area, or has come into contact with other people or equipment; and (iv) cannot determine if a healthcare worker has washed her hands since being in a contaminated area or since coming into contact with other people or equipment. Instead, the GE Hand Hygiene System requires hand-washing every time a healthcare worker enters a room with a monitored dispenser. This is true regardless of the worker's prior location. Hand-washing is required even if the hospital room is empty.

21.   The GE Hand Hygiene System also does not have or distinguish among "zones" such as contamination zones, patient contact zones, or nurse contact zones. As I have stated, every location with a monitored soap dispenser requires hand washing 100% of the time without regard to one's current or previous "zone." I have reviewed paragraphs 9 and 29 of Mr. Wildman's declaration, and he is incorrect in his identification of a "zone manager." Zone manager is a feature of the RTLS OEM RFCODE software that the GE Hand Hygiene System does not use.

22.   The GE RTLS software cannot determine compliance in real-time; compliance is only determined after the Compliance Engine has compared the Location data with the Hand

Hygiene Badge and Dispenser data, which happens only once per day (and which is performed

by software and not by combining the radio frequency signals). I have reviewed paragraphs 24-

27 and 42 of Dr. Felder's declaration, and he is incorrect in his statement that the GE software

determines compliance after each hand-washing event or non-event. GE's Hand Hygiene System

processes data only once per day, as I have explained.

        23.   Further, in the event that a healthcare worker does <u>not</u> wash her hands after

entering or exiting an area with a monitored dispenser, neither the badge nor the dispenser (nor

any other component) sends any signal to indicate that the person did not wash her hands. There

is also no warning flag in the GE Hand Hygiene System, exclamation point, highlighting, or any

other information that is generated to indicate non-compliance. Views of data used to create the

Tableau dashboard charts, and reserved for GE Healthcare authorized persons, are called

underlying data. Underlying data is created during the Tableau dashboard chart creation process.

Underlying data can contain dates and times the staff wearing badges enter and exit a room,

whether they triggered a sanitizer on entry or exit, what hospital unit they are in, duration of time

in the room, staff names, and other indexed data for use by the visualization process. However,

this functionality and information are not included with the accused GE Hand Hygiene system as

sold to the customer, and the customer otherwise has no ability to view or access individual

hand-washing records. The data accessible by the customer only shows aggregated data as I have

explained. The underlying data can be accessed by GE personnel only and is used for support

purposes and not to track hand-washing compliance.

        24.   As a further limitation, the Location radio frequency signals are not combined

with the Hand Hygiene Dispense signals to determine hand-washing compliance or non-

compliance. The reader receives separate signals from the personnel badges and from the

sidecar/embedded module in the dispensers. The reader receives the signals but does not combine them—the signals remain separate and are transmitted to the GE RTLS software as separate data paths. Thus, the badge signals and the dispenser signals operate on separate tracks and transmit separate messages. To emphasize this point, based on the location of the readers, it is possible for a personnel badge to transmit a signal to one reader, while the dispenser used by that same person transmits a signal to a different reader. In this scenario, one reader will forward the signal from the badge to the GE RTLS software, while a separate reader will forward the separate signal from the dispenser. It is also possible for multiple readers to detect a signal from the same badge, but the software is designed to de-duplicate the data when this occurs. I have reviewed paragraph 28 of Mr. Wildman's declaration, as well as Dr. Felder's declaration, and they are incorrect in their identification of "combined signals." As I have explained herein, the GE Hand Hygiene System does not combine any signals from the dispensers, signposts, or personnel badges.

25.   Moreover, the GE Hand Hygiene System does not have a reporting engine for customers that shows in real time individual instances of a person washing or not washing her hands; thus, it is not possible to drill down into the dashboard to see individual instances of when a person did and did not wash her hands. Instead, GE's software only shows aggregate compliance over a period of time. The period of time is defaulted to three months but is customizable to shorter or longer time periods. The shortest time period that can be selected to view aggregate compliance is twenty-four hours. The most recent twenty-four hour period that can be viewed is the twenty-four hours leading up to the most recent daily processing by the Compliance Engine. GE's Hand Hygiene System also does not monitor contact with other people, or contact with or use of equipment.

26.   GE's Hand Hygiene System also cannot use the information provided in the various data streams to electronically search for a person within the facility at any given time. Thus, one cannot search for a person as they move around a facility. The GE RTLS software records in a web app the location where the individual was last seen, but this information is not searchable. This information resides in a portal for the purpose of assigning badges and not searching for people.

27.   As a further limitation, the GE RTLS software is not programmed to determine the time that has elapsed between hand washings of a particular person. The client can only see the total number of opportunities that a person was supposed to wash her hands over a time period, and the percentage of opportunities that the person actually washed her hands.
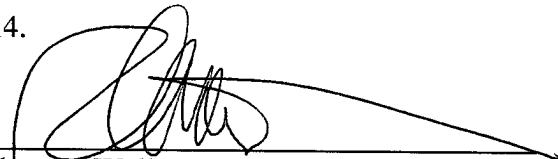
28.   GE's software servers are also incapable of accessing any data concerning hand-washing compliance policies and are instead pre-programmed with the timeframe within which hand washing is required. The Compliance Engine is programmed to perform a retrospective review of the data streams, which involves looking forward and backward the applicable number of seconds. The number of seconds is not customer-changeable to prevent hospitals from adjusting the compliance rate to appear more compliant. I have reviewed paragraph 33 of Mr. Wildman's declaration and paragraph 55 of Dr. Felder's declaration, and it is not correct that a client can change the compliance policy.

29.   The readers in GE's Hand Hygiene System follow an interrupt-based architecture; thus, the readers are not in substantially constant communication with the GE RTLS software. With an interrupt-based architecture, an event must trigger a transmission from the reader to the GE RTLS software. Absent any data transmissions in a particular area at any particular time, the readers are not programmed to communicate any signals to the GE RTLS software. In other

words, the readers do not have a regular pulse and thus are not in substantially constant communication with the GE RTLS software. For example, during nighttime or other periods of low activity, there will be low interaction (or no interaction) between the readers and the GE RTLS software.

30.   Finally, the signposts do not contain receivers and thus do not receive any data of any sort. The signposts are entirely standalone hardware components that are not connected to the GE RTLS software and monitoring network.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct. Executed this 20TH day of June 2014.

Robert L. Wallace

Dated: June 23, 2014

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on June 23, 2014, I will electronically file the foregoing with the Clerk of Court using the CM/ECF system, which will then send a notification of such filing (NEF) to the following:

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